

REMARKS

Status of the Claims

Claims 2-13 are currently pending in the application. Claim 12 has been amended. No new matter has been added

Interview

Applicant thanks Examiner Wang for the courtesies extended to Applicant's personal representative, Carol L. Cole, during the July 8, 2010, telephonic interview.

During the interview, Applicant discussed that aphrons and polyaphrons are a known technology, and as such are art-recognized terms. In support of this position, Applicant again referred the Examiner to U.S. Patent No. 4,486,333 ("the '333 patent"), which although the title refers to biliquid foams, teaches aphrons and polyaphrons at e.g., col. 1, line 39 – col. 2, line 14. Moreover, the Examiner himself cited a patent relating to polyaphrons, i.e., U.S. Patent No. 4,999,198 to Barnett, which on its face recites a journal relating to aphrons. This should be sufficient proof to establish that aphrons and polyaphrons are an art recognized term that the Examiner should acknowledge and give patentable weight.

The Examiner suggested that Applicant should provide a reference that distinguishes a polyaphron from an emulsion, such as that taught by Fukuda. First, Applicant has done so in referencing the '333 patent. See Applicant's response filed April 13, 2009 at pages 5-7. The problem appears to be that the Examiner does not recognize aphrons and polyaphron dispersions as an art recognized technology that is distinct from emulsion technology. Applicant suggested that a USPTO database search

of patents that reference the '333 patent and Barnett (cited below) would establish that a polyaphron dispersion is an art recognized term.

Moreover, Applicant indicated that a simple Google search would reveal several journal articles and company descriptions relating to aphrons.

Applicant's additional comments on the substance of the interview are incorporated into the remarks below.

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected claims 2-9 and 11-13 under 102(b) as being anticipated by U.S. Patent No. 4,254,105 to Fukuda et al. (hereinafter "Fukuda").

The standard under 35 U.S.C. §102 is one of strict identity. "Under 35 U.S.C. §102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." *Getcher v. Davidson*, 116 F.3d 1454, 1457 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." *Richardson v. Suzuki Motor Col., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Applicant respectfully traverses the rejection because Fukuda does not teach every element of the claimed invention.

The Examiner relied on Fukuda for teaching "a multiple emulsion, Fig. 1, having a dispersing form of water-phase/oil-phase/water-phase and the multiple emulsions, i.e., polyaphrons, consisting of a dispersed phase and a dispersion medium." Office Action dated May 27, 2008, at page 2, numbered paragraph 3. In Figure 1, the Examiner stated that the "water/oil emulsion 1 is a dispersed phase (i.e., internal phase) having internal phase 2 dispersed in oil phase 3, and external water phase 4, as a dispersion medium." *Id.* at 3, and citing col. 7, lines 25-29 of Fukuda. The Examiner continued to

argue that the W/O/W emulsion of Fukuda in Fig. 1 clearly meets the claim limitations. Final Office Action dated December 12, 2008, at page 3, numbered paragraph 3, and page 4, numbered paragraph 5.

However, the Examiner has failed to point to the teaching in Fukuda of a polyaphron dispersion, as presently recited. The Examiner appears to be arguing that the water/oil/water emulsion is a polyaphron dispersion. In particular, the Examiner argued that "Fukuda discloses the formation of interfacial film (column 2, lines 39-52)" and stated that "the emulsion of Fukuda is a polyaphron dispersion without using the term of 'polyaphron dispersion.'" Office Action dated April 28, 2009, at 6. However, this is incorrect. As previously argued, a polyaphron dispersion is not the same as an emulsion, as recognized by the materials cited at the beginning of Applicant's specification, as well as the reference cited by the Examiner, and not to mention the wealth of information on aphrons/polyaphrons that can be found on the internet. All of this knowledge on aphrons/polyaphrons indicates that they are separate and distinct from emulsions and for the Examiner to characterize them as the same for the basis of this rejection is error. For at least this reason, the Examiner has failed to establish a *prima facie* case of anticipation based upon Fukuda.

Moreover, the Examiner has failed to point to the teaching in Fukuda of a polyaphron dispersion comprising from about 5 to about 30% by weight, based upon the total weight of the polyaphron dispersion, of an external phase; and from about 70% to about 95% by weight, based upon the total weight of the polyaphron dispersion, of an internal phase. Again, because Fukuda is directed to a water/oil/water emulsion it can

not, and does not, teach a polyaphron dispersion, let alone the specific weight amounts of the various phases of the polyaphron dispersion.

In addition, the Examiner has failed to point to the teaching in Fukuda of a polyaphron dispersion wherein when the internal phase comprises at least two liquid phases, each of the liquid phases is a liquid at room temperature, as presently recited. The only Example in Fukuda which has all liquid components at room temperature is Example 11, which is an emulsion and not a polyaphron dispersion. At most, this example teaches an emulsion with 40 wt.% of a dispersed (or internal) phase. However, this does not teach or suggest the claimed invention, which is directed to a polyaphron dispersion comprising from about 70% to about 95% by weight, based upon the total weight of the polyaphron dispersion, of an internal phase.

The Examiner has repeatedly referred to Example 10 of Fukuda, which is directed to a water/oil emulsion of a nutrient cream. Again, this is not a teaching of a polyaphron dispersion and can not be used as an example that would anticipate the claimed invention. It does not rise to the level of strict identity required to establish a *prima facie* case of anticipation.

Moreover, example 10 does not teach a composition wherein when the internal phase comprises at least two liquid phases, each of the liquid phases is a liquid at room temperature, as presently recited. The materials used in the emulsion are either solid or semi-solid at room temperature based upon their known melting points. So, for at least this reason, Example 10 of Fukuda does not teach the claimed polyaphron dispersion.

For at least these reasons, Fukuda does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claim 10 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fukuda in view of U.S. Patent No. 4,999,198 to Barnett et al. (hereinafter "Barnett"). Applicants respectfully traverse the rejection.

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007):

"Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, "[a]ll claim limitations must be considered" because "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385. According to the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR International Co. v. Teleflex Inc.*, Federal Register, Vol. 72, No. 195, 57526, 57529 (October 10, 2007), once the *Graham* factual inquiries are resolved, there must be a determination of whether the claimed invention would have been obvious to one of ordinary skill in the art based on any one of the following proper rationales:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to

obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007).

Furthermore, as set forth in *KSR International Co. v. Teleflex Inc.*, quoting from *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006), “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasonings with some rational underpinning to support the legal conclusion of obviousness.”

Therefore, if the above-identified criteria and rationales are not met, then the cited reference(s) fails to render obvious the claimed invention and, thus, the claimed invention is distinguishable over the cited reference(s). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because the references, alone or in combination, fail to teach or suggest all the claim elements.

Claim 10 depends from independent claim 12 and is patentable for the same reasons as independent claim 12.

As discussed in detail above, and in prior responses, Fukuda does not teach a polyaphron dispersion, and certainly does not teach all of the claim elements of independent claim 12.

As will be appreciated by the Examiner, emulsions are not the same as biliquid foams. Although they may be composed of hydrophilic phases, hydrophobic phases

and surfactants, their structure is not the same. Emulsions are typically oil droplets suspended in an aqueous medium. The droplet is surrounded by a single layer of surfactant molecules to prevent coalescence with neighboring droplets. If emulsions are diluted, the different phases (as long as they are liquid under the conditions of the experiment) will no longer be stable, and will coalesce into two separate phases, a water and an oil phase. Similarly, if a W/O/W emulsion or an O/W/O emulsion is diluted the separate phases will coalesce and two separate phases will be produced.

In contrast to this, a biliquid foam may be diluted by the addition of more external phase, or continuous phase without the addition of more surfactant without coalescing into two separate phases.

The Examiner is referred to Sebba (US 4,486,333), which is cited on page 1, second paragraph of the application as filed. Professor Felix Sebba of Virginia State University was well known for his work in the field of biliquid foams. Oil-in-water emulsions are distinguished from biliquid foams (polyaphron dispersions) in this document. In particular the Examiner is referred to column 1, lines 31 to 46:

“The water-lamella biliquid foams with which the present invention is concerned are to be distinguished from oil-in water emulsions in which the discontinuous oil phase is separated from the continuous aqueous phase by a single interface. In the composition under consideration, the globules of non-polar liquid are encapsulated in a double surfaced film of hydrogen bonded liquid which is immiscible with the non-polar liquid and contains a soluble surfactant.”

Column 5, lines 61 to 65 where Sebba states that:

“The polyaphrons are characterised by extremely small non-coalescing globules of non-polar liquid. This is because of the encapsulating surfactant film which surrounds each globule and

acts as a barrier to coalescence, thus clearly distinguishing the system from an emulsion."

Second, the Examiner relied on Barnett for supplying this missing teaching of Fukuda. In particular, the Examiner relied on Barnett for teaching that monomers can be added to the external phase and internal phase to perform interfacial polymerization to stabilize the system. Office Action dated April 28, 2010, at pages 4-5. However, this line of reasoning does not rise to the level of a *prima facie* case of obviousness. In particular, the Examiner has failed to point to the teaching in Barnett that overcomes the deficiencies of Fukuda.

Third, Barnett does not teach anything about adding monomers to stabilize its system. The section referenced by the Examiner teaches that polymerization of the polyaphrons stabilizes the system. Moreover, the Examiner has not alleged that Fukuda's emulsion is unstable and needs to be stabilized. Even if that were so, the Examiner has failed to establish why one of ordinary skill in the art of emulsions would look to a patent on polyaphrons for drug delivery in an attempt to solve its stability problem. Further, Barnett recognized its own interfacial instability problems, and promptly taught one of ordinary skill in the art how to fix it. So, one of ordinary skill in the art wouldn't need to look to another reference, such as Fukuda.

In essence, the Examiner has failed to establish how the combination of references teach or suggest all the claim elements, i.e., the elements of claim 10. Moreover, the Examiner has failed to establish the requisite teachings or suggestions that would have motivated one of ordinary skill in the art to modify Fukuda's emulsion technology with Barnett's polyaphron dispersion to arrive at the claimed invention.

For at least these reasons, the Examiner has failed to establish a *prima facie* case of obviousness. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims. This is believed to be a complete and proper response to the Examiner's Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 50-3290.

Respectfully submitted,

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